

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 2, 8, 11, 13, 14, 15 and 16 are currently being amended.

This amendment changes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-16 are now pending in this application with claims 1, 3, 4, 6, 7, 9, 10 and 12 being withdrawn.

Sequence Compliance

In response to the objection, amendments were made to the specification to insert the required SEQ ID NO identifiers associated with each sequence listed. No new matter has been added. Also, submitted with this Amendment and Reply is a Sequence Listing in computer readable form and a paper copy for the specification. Please insert the Sequence Listing filed concurrently herewith following the abstract. The content of the attached paper copy and the attached computer readable copy of the Sequence Listing are the same.

Claim Rejections under 35 U.S.C. § 112

Claims 2, 5, 8, 11 and 13-16 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Office Action asserts that “there would be an unpredictable amount of experimentation required to practice the claimed invention” because (1) “[t]he disclosure does not provide detailed guidance regarding how to accurately predict a “real world” protein or a fragment thereof from a calculation performed on a local part of the primary sequence information of a target protein,” (2) “[t]he disclosure does not provide any working example wherein a “real world” protein structure or fragment thereof was successfully predicted based on a calculation of frustration of a local part of the primary sequence information of said target protein,” (3) the nature of the invention is complex, (4) “[t]he prior art does not show that a tertiary structure of a protein or fragment thereof can be accurately or reliably predicted from primary sequence information,” (5) the skill of those in the art of protein tertiary structure prediction is high, (6) the

predictability of protein tertiary structure from primary sequence information is unknown in the prior art” and (6) “[t]he claims are broad in that they are drawn to predicting any interaction site in any target protein.”

Applicant believes “[a]ny analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention.” MPEP, 8th ed. Rev.2, 2164.01. See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int’l Trade Comm’n 1983), *aff’d. sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

In response, Applicant respectfully submits that the disclosure provides evidence that the structure of a protein or a protein fragment can be predicted from primary sequence information. Applicant directs the Examiner’s attention to Kim T. Simons et al. and Christopher Bystroff et al. which are referenced at least on pages 4 and 5 of Applicant’s specification. In addition, please see Futura et al., cited in Applicant’s IDS filed June 23, 2004.

Furuta et al. discloses a method for calculating a correlation between a secondary structure and an amino acid sequence. Accordingly, Furuta et al. describes methods for

predicting the secondary structure of a protein at a high rate. Simons et al. also discloses a method for determining secondary protein structures.

Further, Simons et al. describes generating tertiary structures using known protein structures with similar local sequences. Simons et al. at 213. In addition, Bystroff indicates that tertiary structures may be generated from local structure predictions. Bystroff at 573. Specifically, Bystroff et al. describes a method for local protein structure prediction based on a library of short sequence patterns. Bystroff's structure prediction protocol is described on page 575. First, Bystroff's process involves submitting the sequence to a server to obtain a set of multiple-aligned sequences. Second, each segment of the profile is tested against each of 82 clusters, and the scores converted to weighted confidences.

Thus, the references cited, together with the specification, provide detailed guidance regarding how to accurately predict a real world protein or protein fragment from a calculation performed on a local part of the primary sequence information of a target protein. Further, by citing Simons et al. and Bystroff et al. the specification provides a working example wherein a real world protein structure or protein fragment was successfully predicted based on a calculation of a local part of the primary sequence information of a target protein.

Applicant further notes that several well known methods exist for predicting tertiary protein structures from amino acid sequences. *See* Simons et al. at 209, 219.

Accordingly, Applicant respectfully requests that the rejection be withdrawn and claims 2, 5, 8, 11 and 13-16 be allowed.

Claim Rejections under 35 U.S.C. § 101

Claims 2, 5, 8, 11 and 13-16 were rejected under 35 U.S.C. § 101 for being directed to non-statutory subject matter. Specifically, the Office Action alleges that claims 2, 5, 8, 11 and 13-16 do not produce a tangible result. Applicant has amended claim 8 to recite a computer readable medium. However, Applicant respectfully traverses the Examiner's rejection concerning the contention that claims 2, 5, 8, 11 and 13-16 do not produce a tangible result.

The invention of claims 2, 5, 8, 11 and 13-16 is directed to a "useful, concrete and tangible result" and is patentable subject matter as set forth in M.P.E.P. § 2106. M.P.E.P. §

2106 IV.C.2.(2) outlines the analysis to be applied to determine whether a claim produces a useful, tangible and concrete result. Three factors must be considered: (a) useful result, (b) tangible result, and (c) concrete result.

First, for an invention to be useful its utility must be (i) specific, (ii) substantial and (iii) credible. Here, claims 2, 5, 8, 11 and 13-16 are directed to an apparatus, computer program and method for predicting an interaction site in a target protein based on a frustration of a local part of the primary sequence information on the target protein. Accordingly, the claimed technique may be used to predict an interaction site in a target protein. Applicant respectfully submits that the claimed invention for predicting an interaction site in a target protein is therefore useful.

Second, for the invention to be tangible it must produce a real-world result. However, the tangible requirement does not mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing as the office action seems to suggest. *See* The Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility at p. 21. The claimed invention can be used to predict an interaction site in a target protein. The ability to predict an interaction site in a target protein is a substantial practical application. Accordingly, Applicant respectfully submits that the claimed technique recites a tangible result.

Third, for the claim to recite a concrete result, the process must have a result that can be substantially repeatable or must substantially produce the same result again. *See In re Swartz*, 232 F.3d 862, 864 (Fed. Cir. 2000). The claimed technique is directed to predicting an interaction site in a target protein. The technique can be repeated and, depending upon the quality of the acquired data, can substantially produce the same result. Accordingly, Applicant submits that the claimed technique recites a concrete result.

In summary, claims 2, 5, 8, 11 and 13-16 satisfy all three factors that must be considered when analyzing a claim under M.P.E.P. § 2106 IV.C.2.(2), to determine whether a claim satisfies 35 U.S.C. § 101.

In the Office Action, the Examiner suggests that the rejection could be overcome by amendment of the claims to recite that a result of the application “is outputted to a display, a

user, a readily accessible memory or other computer on a network.” While Applicant thanks the Examiner for this suggestion, the Applicant can find no legal support for the position that a method or algorithm is patentable subject matter only if the data produced by an algorithm is output, displayed or stored. Instead, Applicant submits that the determination of an interaction site in a target protein as claimed is a tangible, concrete and useful result. Under current U.S. law, whether or not this determination is then subsequently saved or displayed is not essential to inquiry under 35 U.S.C. § 101. Further, Applicant finds no support for the Examiner’s position and suggestion in The Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility.

Accordingly, Applicant respectfully requests that the rejection be withdrawn and claims 2, 5, 8, 11 and 13-16 be allowed. Further, if this rejection is maintained Applicant refers the Examiner to MPEP § 2106 which states “[i]t is essential that patent applicants obtain a prompt yet complete examination of their applications. Under the principles of compact prosecution, each claim should be reviewed for compliance with every statutory requirement for patentability in the initial review of the application, even if one or more claims are found to be deficient with respect to some statutory requirement. Thus, Office personnel should state all reasons and bases for rejecting claims in the first Office action. A failure to follow this approach can lead to unnecessary delays in the prosecution of the application.” (emphasis added.)

Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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